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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,871	10/20/2000	Alexandre Marti	NITROS P146US	6986

7590 12/05/2002

Davis and Bujold  
Fourth Floor  
500 North Commercial Street  
Manchester, NH 03101

EXAMINER
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SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/05/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/673,871

Applicant(s)

MARTI ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Amendment filed on October 02, 2002 has been entered. Claims 19-35 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments.

Applicant's arguments filed October 02, 2002 have been fully considered but they are not persuasive for the reasons set forth below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 19-23, 25-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Gierskcky et al WO 96/28412 ('412).

Applicant argues that the solution disclosed in '412 is for prepration in the sense of synthesis not administration and that the instant claims are directed to solutions for therapeutic or diagnostic purposes. (see Response p.5).

In response, and as explicitly stated in the previous Office Action, the instant claims are directed to solutions comprising ester of 5-aminolevulinic acid at concentrations lower than 1%, not pharmaceutical nor diagnostic compositions. Intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. (see page 4 of Paper No. 8).

Further, Examiner states that the instant claims 29-35 appear to be drafted as "product by process" claims. Accordingly, product by process claims are not limited to

Art Unit: 1617

the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113.) "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

WO '412 disclose solutions containing 5-aminolevulinic acid (ALA) esters in concentrations lower than 1% wt (see examples 1-3). Example 1 utilizes 1 g of ALA in 200 ml of methanol leading to a 0.5% wt solution. WO '412 also disclose the use of chelators such as EDTA, or deferoxamine etc.. in the final preparation to reduce toxicity associated with therapeutic use of ALA (see page 13, 25). There is no elemental difference between the limitations of the instant claims and the solutions disclosed in WO '412, thus, WO patent anticipates all the limitations of the instant claims regardless of the intended use.

2. Claims 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '412 in view of Chang et al (Journal of Photochemistry and Photobiology 1997;28 (2-3): 114-22).

Applicant argues that WO '412 are not directed to solutions for the claimed use. Further, Applicant states that Chang's solutions are not directed to esters of ALA.

First, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the

Art Unit: 1617

rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the rejection is based on the combined teachings of the references not their individual features.

Accordingly, as recognized by the Applicant's the only difference between WO and the instant claims are in the claimed explicit recitation of the intended use. Such shortcoming is alleviated in view of Chang's teaching. Chang discloses the use of therapeutic formulations of ALA having lower concentrations of about 1%. Further, Applicant's arguments that Chang does not specifically recite the therapeutic use of ALA-esters is not persuasive, because further the instant claims are not absolute to such characteristic. The instant claims are directed to solutions of ALA-esters. Contrary to Applicant's assertion that there is a significant structural difference between ALA and its esters, Examiner replies that it has long been established in the art that esters disassociate in an aqueous solution and exist in equilibrium with their elemental moieties. (see Basic Chemistry Worth Publisher, Inc. p.420, table 17-3).

Furthermore, as explained in the references 2 and 8 submitted along with the amendment, Paper no. 10, the therapeutic use Ala-Esters has long been established (see reference 2, Lange et al, at page 185, last para. And reference 8, Cases et al, page 1794, 2<sup>nd</sup> col, line 10-14). Thus, application of ALA-esters for diagnostic or therapeutic use has been well known to one of ordinary skill in the art. Subsequently, absence of showing a unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to use the solution of ALA esters taught in

Art Unit: 1617

WO '412 at lower concentration or suitable pH by routine optimization, because as suggested by Change, lower concentrations of ALA are effective as photosensitizers for photodynamic therapy. Therefore, there would have been expectation of success in using the solutions of WO '412 at lower concentration for phototherapy.

Finally, in response to commercial utility of the instant claims, Examiner responds that such arguments do not address the patentability of the subject matter claimed.

Accordingly, the rejection is proper.

3. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "the solvent" in 1. There is insufficient antecedent basis for this limitation in the claim.

### ***Conclusion***

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1617

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss  
December 2, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200